REMARKS

Applicants are filing this Preliminary Communication to Accompany Request for Continued Examination in order to respond to the points raised by the Examiner in the Advisory Action mailed 7 January 2010.

Applicants wish to make it clear that the alendronate granules disclosed in the USLU et al reference and the alendronate microparticles employed according to the presently claimed invention are very different. First of all "granule" and "microparticle" are conceptually two distinct technical terms used in pharmaceutical technology to describe two different products. Therefore discussing the difference between "granules" and "microparticles" solely in terms of particle size does not accurately describe all of the reasons why "granules" and "microparticles" differ from one another. The definitions of these two terms require further elaboration and clarification.

Microparticles are coated by encapsulation with a polymer matrix and are commonly used for drug delivery systems, such as sustained or controlled release, local delivery and pulsatile delivery in pharmaceutical technology. Although these microparticle systems are widely known for their use in controlled

drug delivery systems, they have several different applications, including:

taste and odor masking,

protection of drugs from the environment,

particle size reduction for enhancing solubility of poorly soluble drugs, and

cell encapsulation.

See Park, K., Yeo, Y., "Microencapsulation Technology" in Encyclopedia of Pharmaceutical Technology ed., Swarbrick, J., p. 2315.

In the present case, Applicants are taking advantage of this technique by encapsulating microparticles of alendronate with polymers, such as Eudragit® in order to prevent esophageal irritation. Therefore, it is not the particle size of the microparticles per se that Applicants are using to obtain their advantageous result; rather it is the whole process for coating the microparticles to produce the microencapsulated alendronate that is the key to the invention. In other words according to the presently claimed invention Applicants are using the microencapsulation process, rather than a basic granulation method as disclosed in USLU et al, to obtain a very different product from the granules disclosed in USLU et al. Thus the coated microparticles according to the present invention are not the same

and are not the equivalent of the granules employed according to USLU et al.

Furthermore in the "Microencapsulation Technology" text, it has been taught that the microencapsulation technique produces small particles ranging from 1 to 1000 μm. The resulting particles can be named as microparticles, microspheres, microcapsules, and micromatrices. See page 2315, right-hand column, last paragraph.

On the other hand granulation processes are well known in the pharmaceutical industry in order to enlarge and increase the density of small particles. See Parikh, D.M., Handbook of Pharmaceutical Granulation Technique, Marcel Dekker, Inc., New York 1997; Miller, R.W., Sheskey, P.J., "Roller Compaction technology for the Pharmaceutical Industry" in Encyclopedia of Pharmaceutical Technology ed, Swarbrick, J., p. 3159. Granulation is defined as "A size enlargement process during which small particles are formed into larger, physically strong agglomerates in which the original particles can still be identified." It is apparent from this definition that the resulting granules are the agglomerated particles. The reference also teaches that pharmaceutical granules are used primarily for tableting and also that the granules may be dispersed in packets and capsules. According to the reference, the objective for carrying out granulation is to improve the flow properties of the pharmaceutical ingredient, as well as to improve

the compression characteristics, and for preventing segregation of the constituents. Also the physical properties of the granules, such as granule density, and granule size are also controllable. See Augsburger, L.L., Vuppala, M.K., "Theory of Granulation" in Handbook of Pharmaceutical Granulation Technique, ed., Parikh, D.M., pp 7 to 9.

It is clear from the definitions that the terms "granules" and "microparticles" are totally different subjects in pharmaceutical technology. It is also clear that none of the references cited by the Examiner, including USLU et al, WATANABE et al, BLACK et al, TRITTHART et al, BARRY et al, or the combination thereof discloses or suggests microparticles of alendronate either per se or coated with a polymer such as Eudragit® yo form microencapsulated alendronate.

Applicant has requested suspension of the prosecution of this application for a period of three months in order to give the Applicant sufficient time to hold a telephone interview with the Examiner.

Applicant looks forward to arranging the telephone interview between the Examiner and the Undersigned. In the meantime Applicant is providing for payment of the cost of filing this RCE along with a two month extension of the term for response to be charged to the credit card of the undersigned attorneys. The cost of $130 for obtaining the three month suspension of the prosecution of this RCE application may be charged to the deposit account of the undersigned attorney 18-2025.

Applicants believe that all claims now presented are allowable over the cited prior art and earnestly solicit a response to that effect.

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4 References